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APR 2 4 2003

510(k) Summary

Date
March 26, 2003

Submitter
PLUS Orthopedics
6055 Lusk Blvd
San Diego, CA 92121

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name
Hip stem

Classification name
Prosthesis, hip, semi-constrained, metal/polymer, uncemented
LWJ per 21 CFR Sec. 888.3360

Equivalent Device
The Modular PLUS® Revision Hip system with modifications have the same indications and fundamental scientific technology, and similar materials as the Modular PLUS Revision stem cleared on K994126.

Device Description
The Modular PLUS Revision stem is a cementless two part modular system that consists of a distal anchorage module and proximal revision module, connected by a multistage tapered coupling, secured by a cylindrical screw.

A total of 96 different anatomically-matched stems can be combined for the left and right hips by using 24 distal and 6 proximal modules.

The Modular PLUS stem system is manufactured from Ti-6Al-4V alloy that conforms to ASTM F136. The surface is grit blasted with corundum to produce a surface roughness of 4-6μm.

Intended Use
The Modular PLUS Revision Stem is intended for cementless use in fractures of the femur where a long section of bone is damaged and the stem must anchor into the distal half of the femur.

Summary of Technological Characteristics Compared to Predicate Device
The Modular PLUS Revision stem is similar to the Modular PLUS Revision stem cleared on K994126. Both stems have the same overall stem profile and are manufactured from similar titanium alloys (Ti6Al4V – new design & Ti6Al7Nb – original design). The indications for use are the same for both stems. The only difference are the minor change in material, increase in diameter of coupling taper, anodization of coupling taper, and slight modification of connecting screw.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2003

PLUS Orthopedics
c/o Mr. J. D. Webb
1001 Oakwood Boulevard
Round Rock, TX 78681

Re: K030971
Trade/Device Name: Modular PLUS® Revision Stem
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: LWJ
Dated: March 26, 2003
Received: March 28, 2003

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Milhem

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K030971

Device Name: Modular PLUS Revision Stem

Indications for Use:

Modular PLUS Revision Stem
Indications for Use

The Modular PLUS® Revision Stem is intended for cementless use in fractures of the femur where a long section of bone is damaged and the stem must anchor into the distal half of the femur.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____(Division Sign-off)
Division of General, Neurological and Restorative Devices

510(k) Number_____

Prescription Use Yes
(per 21 CFR 801.109) OR Over-the-Counter Use No

(Optional format 1-2-96) _____

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030971